Biobor
Interim Registration Review Decision
Case Number 3029

March 2019

Approved by: _____

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Acting Director
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I. Introduction

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for biobor (case 3029, PC codes 012401 and 012402) and is being issued pursuant to 40 CFR sections 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may: 1) require new risk mitigation measures; 2) impose interim risk mitigation measures; 3) identify additional data or other information required to complete the review; and 4) include schedules for submitting the required data, conducting the new risk assessment, and completing the registration review. For further information on biobor, additional documents can be found in EPA's public docket (EPA- HQ-OPP-2008-0453) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States generally must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

EPA is issuing an Interim Decision for biobor so that it can move forward with aspects of the registration review that are complete. EPA determined that no pollinator exposure and effects data are necessary to make a final registration review decision for biobor. The Agency has evaluated risks to listed species and is making a "no effect" finding for listed species and designated critical habitat and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required. The Agency will complete endocrine screening for biobor, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) 408(p), before completing this registration review. See Appendices A and B, respectively, for additional information on the endangered species assessment and the endocrine screening for the registration review of biobor.

This document is organized in five sections: the *Introduction*, which includes this summary and highlights of significant events that have occurred during the registration review of biobor; *Use and Usage*, which describes how and why biobor is used and summarizes data on its use; *Scientific Assessments*, which summarizes EPA's human health and ecological risk assessments and updates or revisions to previous risk assessments; the *Interim Registration Review Decision*, which describes the regulatory rationale for EPA's registration

review decision; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

A. Summary of Biobor Registration Review

Pursuant to 40 CFR section 155.50, EPA formally initiated registration review for the biobor chemical case in 2008. The following highlights significant events that have occurred during the registration review of biobor and can be found in EPA's public docket, EPA- HQ-OPP-2008-0453, accessed at www.regulations.gov:

- September 2008 - Publication of the *Biobor Preliminary Work Plan* (PWP) for a 60-day public comment period. No comments were received on the PWP.

- March 2009 - Publication of the *Biobor Final Work Plan* (FWP).

- May 2012 - The Agency issued two Generic Data Call-Ins (GDCIs) for biobor on May 14, 2012: GDCI-012402-1088 and GDCI-012401-1087. All data have been reviewed and the data requirements are satisfied.

- May 2018 - The Agency published the *Registration Review Preliminary Risk Assessment for Biobor* for a 60-day public comment period. The Agency received two public comments. The comments did not change the data needs, risk assessment, or the timeline for the registration review.

- December 2018 - The Agency published the *Biobor Proposed Interim Registration Review Decision* for a 60-day public comment period. No public comments were received.

- March 2019 - The Agency has completed the *Biobor Interim Registration Review Decision* and will announce its availability in the Federal Register in docket EPA-HQ-OPP-2008-0453.

II. Use and Usage

The first product containing biobor as a fungicide was registered in the United States in 1965. A Reregistration Eligibility Decision (RED) was issued by the Agency for biobor in 1993 as a fungicide used in the fuel tanks and fuel lines of vehicles, farm equipment and industrial engines to prevent the growth of microbial organisms such as slime-forming bacteria and fungi, which could interfere with the unloading, use and quality of non-gasoline fuels. Biobor is sold in packages that include 8-, 16-, and 32-ounce bottles, one- and five-gallon pails, 55-gallon drums and 330-gallon totes. The Agency concluded that biobor posed no risks of concern when used according to EPA-approved product labeling. After the risk assessments were completed to support the RED, registered uses were expanded to include wood preservatives for use in seasoned wood during non-pressure wood treatment and biocide treatment of non-fuel hydrocarbon products including hydraulic fluids, transmission fluids, lubricating oils, lubricants and antifreeze. The wood preservative use was cancelled in 2014[1] and is therefore no longer addressed in this registration review.

[1] https://www.federalregister.gov/documents/2014/10/17/2014-24646/notice-of-receipt-of-requests-for-amendments-to-delete-uses-in-certain-pesticide-registrations

III. Scientific Assessments

A. Human Health Risk

A summary of the Agency's human health risk assessment is presented below in support of the registration review of biobor. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of biobor. For detailed discussions of all aspects of the human health assessment, see the *Registration Review Preliminary Risk Assessment for Biobor* located in the public docket at EPA-HQ-OPP-2008-0453.

1. Summary of Human Health Risks and Risk Characterization

In the FWP for biobor (docket number EPA-HQ-OPP-2008-0453), the Agency determined that the boric acid database is appropriate to select toxicology endpoints for biobor. Given the rapid decomposition of biobor to boric acid, the moiety of toxicological concern is therefore boric acid. The toxicity database for boric acid was evaluated in the Boric Acid Risk Assessment (docket number EPA-HQ-OPP-2009-0306).

There are no dietary and drinking water exposures to biobor; therefore, these routes of exposure were not evaluated. In addition, there are no toxicological endpoints of concern for dermal exposure to biobor. However, because there is an inhalation endpoint for boric acid, residential[2] and occupational handler inhalation exposure assessments were conducted for open pouring of biobor.

Residential Handler Risks:

Biobor is sold in packages that include 8- 16- and 32-ounce containers, and the use sites listed on the label include home heating oil tanks and boats. Thus, there is the potential for residential handler exposure during the use of biobor to treat home heating oil and diesel fuel used in recreational boats. These exposures were evaluated using the Margin of Exposure (MOE) approach as shown in Table 1. It was assumed that 300 gallons, which the Agency believes is the average size of home heating oil or marine diesel fuel tanks, would be treated at the maximum labeled application rate of 270 ppm. The resulting MOE of 11,000,000 is not of concern because it exceeds the target MOE of 100 for inhalation. The target MOE for inhalation is 100 because there is a 10x uncertainty factor for data extrapolation from animal to human (interspecies) and a 10x uncertainty factor for the potential variation in sensitivity among members of the human population (intraspecies).

[2] Residential exposure exists; however, it was not evaluated in the *Registration Review Preliminary Risk Assessment for Biobor*. The residential risk assessment has now been conducted and was included in the PID.

Table 1 – Residential Handler Inhalation MOE for the Use of Biobor

Amount Product Handled per Day	Amount Boron Handled per Day[B]	Unit Exposure[C]	Exposure[D] (mg/day)	Daily Dose[E] (mg/kg/day)	Inhalation MOE[F] (Target = 100)
8 ounces[A]	0.040 lbs	0.0017 mg/lb ai	0.000068	0.00000085	11,000,000

A. Is enough to treat 300 gallons of diesel fuel at the maximum application rate of 270 PPM.
B. Amount Boron Handled = Number of Gallons * 8.75 lb/gallon * 95% Biobor * 7.7% Boron in Biobor
C. Estimated arithmetic mean for the conventional pour scenario from AEATF II Liquid Pour Study.
D. Exposure = Amount ai Handled × Unit Exposure.
E. Daily Dose = Exposure (mg/day)/Body Weight (80kg).
F. MOE = POD / Exposure where the inhalation POD is 9.6 mg/kg/day

Residential Post-Application Risks:

The use of biobor to treat heating oil and recreational boat fuel (at maximum application rate of 270 ppm) is not expected to result in residential post-application exposure. The Agency believes residential post-application risk would be minimal.

Aggregate Risks

In accordance with the Food Quality Protection Act (FQPA), the Agency must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or population adjusted dose [PAD]), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, the Agency considers both the route and duration of exposure. For biobor, there are no dietary or drinking water exposures. Based on the extremely low risk calculated for the residential fuel treatment use for biobor, there is minimal increase to the aggregate inhalation risk for the uses of boric acid (as the boric acid endpoint was used to assess biobor).

Cumulative Risks

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for boric acid[3] and any other substances, and boric acid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this risk assessment, therefore, EPA has not assumed that biobor has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance- human-health-risk-assessments-pesticides#risk-assessment.

[3] In the biobor draft risk assessment (DRA), the Agency determined that, based on the chemistry of biobor, the toxicology database for boric acid and salts would be used to characterize the risk from potential exposure to biobor.

Occupational Handler Risks:

The label indicates that the preferred method of blending the appropriate concentration is by metered injection directly into the stream of flowing fuel as it is added to a fuel tank. However, occupational inhalation exposure can occur because the label allows open pouring of biobor. These exposures were evaluated using the Margin of Exposure (MOE) approach. Because the amount of product that could be handled by one person in a day is not known, a range of amount handled values were used to calculate the MOEs as outlined in the table below. The MOEs range from 36,000 when 20 gallons of product are handled to 6,900 when 100 gallons of product are handled. In addition, the amount of product handled per day was backcalculated based on the target MOE of 100. In order to reach the target MOE of 100, 7,040 gallons of product would have to be handled per day, which is highly unlikely to occur in an "open pouring" use pattern. It is more likely that amounts greater than 100 gallons would be metered in from 55-gallon drums or 330-gallon totes rather than being open poured. Given that inhalation MOEs are not below the target MOE of 100, inhalation exposure is not a risk of concern.

Amount Product Handled per Day	**Amount Boron Handled per Day[D]**	**Unit Exposure[E]**	**Exposure[D] (mg/day)**	**Daily Dose[E] (mg/kg/day)**	**Inhalation MOE[F] (Target = 100)**
20 gallons[A]	12.8	0.0017 mg/lb ai	0.022	0.00027	36,000
100 gallons[B]	64 lb		0.11	0.0014	6,900
7,040 gallons[C]	4500 lb		7.65	0.096	100

A. Assuming four 5-gallon containers which is the maximum amount handled in the AEATF II Liquid Pour Study (MRID 48917401)
B. Assuming twenty 5-gallon containers. Is enough to treat 500,000 gallons of fuel (6.7 lb/gallon) at 270 ppm.
C. Back calculated from the target MOE of 100. Is enough to treat 35,000,000 gallons of fuel at 270 ppm.
D. Amount Boron Handled = Number of Gallons * 8.75 lb/gallon * 95% Biobor * 7.7% Boron in Biobor
E. Estimated arithmetic mean for the conventional pour scenario from AEATF II Liquid Pour Study.
F. Exposure = Amount ai Handled × Unit Exposure.
G. Daily Dose = Exposure (mg/day)/Body Weight (80kg).
H. MOE = POD / Exposure where the inhalation POD is 9.6 mg/kg/day

2. Human Incidents

Based on a search conducted on August 8, 2018, there are no reported human health incidents from the use of a biobor product in the Office of Pesticide Programs' (OPP) Incident Data System (IDS) database for the time period spanning from 1992-2018.

3. Dietary Exposure/Tolerances

Biobor has no uses involving direct or indirect dietary exposure. Therefore, a dietary exposure and risk assessment is not needed for registration review and a tolerance or tolerance exemption is not required.

B. Environmental Risk

A summary of the Agency's environmental risk assessment is presented below in support of the registration review of biobor. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of biobor. For detailed discussions of all aspects of the ecological assessment, see the *Registration Review Preliminary Risk Assessment for Biobor* located in the public docket at EPA-HQ-OPP-2008-0453 at www.regulations.gov.

1. Summary of Ecological Risks and Risk Characterization

Due to the use of biobor as an additive to hydrocarbon fluids and the rapid hydrolysis of the parent compound to boric acid, the ecological risks from biobor are expected to be minimal. Any potential exposure would be a result of misuse or accidental discharge into the environment, and the data suggest that the ecological impact would be minimal even in these cases.

Biobor was found to have low toxicity to non-target organisms coupled with low exposure potential and rapid degradation to boric acid. Due to a lack of exposure and low toxicity of boric acid, biobor is not expected to cause adverse effects to non-target organisms, including listed species and designated critical habitat. Therefore, the Agency is making a "no effect" finding for listed species based on the use of biobor in hydrocarbon fluids (see Appendix A). Also, EPA has determined that no pollinator exposure and effects data are necessary to make a final registration review decision for biobor.

2. Ecological Incidents

Based on a search conducted on February 7, 2018, there are no reported environmental incidents from the use of biobor products in OPP's IDS database for the time period spanning from 1996-2018.

3. Ecological and Environmental Fate Data Gaps

For the registered biobor uses in hydrocarbon fluids such as hydraulic fluids, transmission fluids, lubricating oils, lubricants, and antifreeze, there are no outstanding ecological or environmental fate data for biobor.

IV. Interim Registration Review Decision

A. Risk Mitigation Measures and Regulatory Rationale

In accordance with 40 CFR sections 155.56 and 155.58, the Agency is issuing the *Biobor Interim Registration Review Decision*. Except for the Endocrine Disruptor Screening Program (EDSP), the Agency has made the following Interim Registration Review Decision: (1) no additional data are needed at this time, and (2) changes to the affected registrations or their labeling are not needed at this time.

In this *Biobor Interim Registration Review Decision*, the Agency has made a "no effect" determination under ESA for biobor. The Agency is making no human health or environmental

safety findings associated with the EDSP screening of biobor. The Agency's final registration review decision for biobor will be dependent upon an EDSP FFDCA section 408(p) determination.

1. Human Health and Ecological Risks

In the *Registration Review Preliminary Risk Assessment for Biobor*, the Agency determined that there are no human health and ecological risks of concern for the uses of biobor. Therefore, risk mitigation measures are not needed at this time.

V. Next Steps and Timeline

A. Interim Registration Review Decision

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing the *Biobor Interim Registration Review Decision*. A Federal Register Notice will announce the availability of this Interim Decision. The Agency determined that no pollinator exposure and effects data are necessary to make a final registration review decision for biobor. As indicated in Appendix A, the Agency has made a “no effect” determination under ESA for biobor, and in Appendix B, the Agency’s final registration review decision for biobor will be dependent upon the result of the EDSP FFDCA section 408(p) determination.

B. Implementation of Mitigation Measures

This Interim Decision does not include any mitigation measures for biobor.

VI. Appendices

Appendix A: Endangered Species Assessment

The Agency has no expectation for the registered pesticide uses of biobor to cause direct or indirect adverse effects to threatened and endangered species. The Agency is making a “no effect” determination for biobor under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required.

Appendix B: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for biobor, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), biobor is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[4] and includes some pesticides scheduled for registration review and chemicals found in water. Biobor is not currently scheduled for screening. However, it should be noted that biobor will be screened for its potential to interact with the endocrine system. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[5]

In this interim decision, EPA is making no human health or environmental safety findings associated with the EDSP screening of biobor. Before completing the registration review for biobor, the Agency will make an EDSP FFDCA section 408(p) determination.

[4] See https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[5] http://www.epa.gov/endo/